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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,334	06/19/2001	Sylvain Chemtob	2861-4003	9475
27123	7590	12/06/2004	EXAMINER	
MORGAN & FINNEGAN, L.L.P.			LANDSMAN, ROBERT S	
3 WORLD FINANCIAL CENTER			ART UNIT	
NEW YORK, NY 10281-2101			PAPER NUMBER	
			1647	

DATE MAILED: 12/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

**Application No.**

09/787,334

**Applicant(s)**

CHEMTOB ET AL.

**Examiner**

Robert Landsman

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 6-9 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-5 and 10 is/are allowed.
- 6) ☒ Claim(s) 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***1. Formal Matters***

- A. The Amendment dated 11/10/04 has been entered into the record.
- B. Claims 1-10 are pending. Claims 6-9 have been withdrawn as being drawn to a non-elected invention. Therefore, claims 1-5 and 10 are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### ***2. Specification***

- A. The objection to the specification under 35 USC 132 has been withdrawn in view of Applicants' arguments and identification as to where support can be found in the specification as originally filed. TO clarify, the term "variant" can be found on page 13, line 20. The phrase "comprising one or more sequences" has support on page 4, lines 29-30 since it is clear that the antagonist can comprise "sequences." Support for the phrase "in which one or more amino acids can be substituted or deleted" can be found on page 15 where Applicants teach that they have substituted all the L-amino acids with D-amino acids. Furthermore, "consisting essentially of" is clearly supported given the use of these other terms, as well as previously recited language such as "comprising."

### ***3. Claim Rejections - 35 USC § 112, first paragraph – new matter***

- A. The rejection of claims 1-5 and 10 under 35 USC 112, first paragraph, regarding new matter has been withdrawn for the reasons discussed in Section 2 of this Office Action.

### ***4. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement***

- A. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the antagonists of claim 1 and those on page 15 of the specification, does not reasonably provide enablement for antagonists in which potentially every amino acid can be substituted.. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The breadth of the claims is excessive. As written, the peptides could have every amino acid altered. Applicants have only provided guidance and working examples of peptides in which all L-amino acids have been replaced with D-amino acids, as well as only a few very specific single amino acid

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changes (page 15, lines 15-19). The peptides of SEQ ID NO:1-11 and 13-15 are very similar in structure (e.g all begin with I L A/G H/F/W/A R/K, etc.). The amino acid changes among the peptides are limited. However, the way the claim is worded, there is no requirement for maintaining any of this structure as long as the peptide is an antagonist. Finally, the limitation "consisting essentially of" is open language. Therefore, no size limitations are placed on the peptide, not that remedying this issue will make the claims allowable. Furthermore, it is not predictable to the artisan what changes can be made to maintain the functional characteristics of these peptides.

Therefore, in summary, the breadth of the claims is excessive with regard to Applicants claiming all peptide antagonists which do not have to have any structural relation to SEQ ID NO:1-11 and 13-15. Applicants only provided guidance and working examples of changing L- to D-amino acids and a couple specific changes (G-A and G-P). Due to this lack of guidance it is not predictable to the artisan what changes can be made to the peptides to maintain their functional characteristics. Therefore, the Examiner holds that undue experimentation is required to practice the invention as claimed.

#### ***5. Claim Rejections - 35 USC § 112, second paragraph***

A. The rejection of claim 3 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendment to the claims.

#### ***6. Claim Rejections - 35 USC § 102***

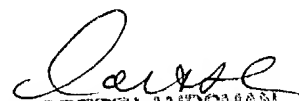
A. The rejection of claims 1 and 5 under 35 USC 102 has been withdrawn in view of Applicants' amendment to the claims to recite "consisting of."

#### ***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 9 AM-6 PM (eastern); alt F 9 AM-6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
ROBERT LANDSMAN  
PATENT EXAMINER